

Claims

1. A film coating composition suitable for use in coating pharmaceutical formulations comprising a dispersion comprising:

- a) an acrylic polymer, which is Eudragit<sup>®</sup> NE30D
  - 5 b) an anti-sticking agent, which is glyceryl monostearate (GMS)
  - c) a surface active agent wherein the surface active agent is in an amount less than 1.3 % by weight of the dispersion, and
  - d) a water-containing liquid,
- wherein the dispersion does not contain a vinyl acetate polymer.

10 2. A film coat covering a pharmaceutical core wherein the core comprises a pharmacologically active ingredient and optionally one or more pharmaceutically acceptable excipients wherein the film coat comprises:

- a) an acrylic polymer, which is Eudragit<sup>®</sup> NE30D
  - 15 b) an anti-sticking agent, which is glyceryl monostearate (GMS)
  - c) a surface active agent, wherein the surface active agent is in the amount less than 5.4 % by weight of the weight of the film coat,
- wherein the film coat has been deposited from a water-containing liquid and does not contain a vinyl acetate polymer.

20 3. A pharmaceutical formulation comprising:

- a) a pharmaceutical core comprising a pharmacologically active ingredient and optionally one or more pharmaceutically acceptable excipients, and
  - b) a film coat comprising:
    - 25 i) an acrylic polymer, which is Eudragit<sup>®</sup> NE30D
    - ii) an anti-sticking agent, which is glyceryl monostearate (GMS) , and
    - iii) a surface active agent, wherein the surface active agent is in the amount less than 5.4 % by weight of the weight of the film coat,
- wherein the film coat has been deposited from a water-containing liquid and does not
- 30 contain a vinyl acetate polymer.

4. A pharmaceutical formulation comprising a pharmacologically active ingredient which is provided in a plurality of beads which optionally contain one or more pharmaceutically acceptable excipients wherein each of the beads is coated with a film coat as defined in claim 2.

5. A formulation according to either claims 3 or 4 wherein the formulation is a modified release formulation.

6. A formulation according to any one of claims 3, 4 or 5 wherein the pharmacologically active ingredient has activity in the treatment of cardiovascular diseases.

7. A formulation according to claim 6 in which the pharmacologically active ingredient is a beta-blocking adrenergic agent.

8. A formulation according to claim 7 in which the pharmacologically active ingredient is metoprolol or a pharmaceutically acceptable salt thereof.

9. A formulation according to claim 8 in which the metoprolol salt is a tartrate, succinate, fumarate or benzoate salt .

10. A composition as claimed in claim 1 wherein the liquid is water.

11. A process for the preparation of a film coating composition according to claim 1 comprising mixing together the acrylic polymer dispersion, the anti-sticking agent, the surface active agent, and the liquid at a temperature in the range of 10 to 100°C.

12. A process to prepare a formulation as claimed in claims 3 to 9 comprising coating the pharmaceutical core with a film coating composition as defined in claim 1.

13. A process to prepare a formulation as claimed in claims 3 to 9 comprising coating the plurality of beads with a film coating composition as defined in claim 1.